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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/789,139

02/27/2004

Kevin P. Connors

ALTU-1110

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08/18/2009

Cutera c/o MoFo

425 Market Street

San Francisco, CA 94105-2482

EXAMINER

SHAY, DAVID M

ART UNIT

PAPER NUMBER

3769

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DELIVERY MODE

08/18/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/789,139	<b>Applicant(s)</b> CONNORS ET AL.	
	<b>Examiner</b> david shay	<b>Art Unit</b> 3769	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on June 4, 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 15-17,22,33 and 40-43 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-17,22,33 and 40-43 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>June 4, 2009</u> .  | 6) <input type="checkbox"/> Other: _____                          |

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This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

With regard to the rejection, applicant argues that because Altshuler et al ('3042) teaches a producing temperatures in the range of 37.5 to 41 degrees Celsius, the reference teaches something "quite different" from the claimed invention, which requires the tissue to be raised to a temperature of at least 50 degrees Celsius. As Altshuler et al ('3042) is the base reference in the combination, this argument is convincing. It is noted, however, that the claimed parameters, with the exception of the tissue temperature are taught by Altshuler et al ('3042)

Applicant has also submitted a Declaration from Scott A. Davenport (hereinafter Declarant), which the examiner will now discuss. In the first paragraph, Declarant states that he is the vice president of research for Cutera (this appears to be the assignee of record, which is recorded as Cutera, Inc. at reel/frame 015631/0749), and at paragraph 2, notes that Cutera sells light based systems for the treatment of various dermatological conditions, with the initial product offering being laser based. Declarant further notes, in paragraph 3, that a subsequent product based on a flash lamp was then produced.

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Continuing, Declarant states in paragraph 4, that a product for tightening skin was then worked on, with the goal being a device that would tighten the skin in a uniform manner, produce an aesthetic result, cause minimal pain, and be easy to use.

In paragraph 5, Declarant notes that first the desired wavelength range to be used was established and found to be in the 1050nm to 1850 nm range, however, the commonly used products at the time produced comparatively little radiation in this range.

In paragraph 6, Declarant discusses the decision to employ a “custom halogen bulb with appropriate filtering” as the light source, noting that the wavelength band discussed in paragraph 5 achieved tissue heating from 1-3.5 mm deep.

In paragraph 7 Declarant states that he is not aware of any device operating in the waveband discussed above and producing long pulses of broadband light for skin tightening, and further asserts that selection of the lamp, wavelength range, and treatment parameters “occurred only after significant modeling and experimentation” and further states the opinion that these choices were not obvious in view of the earlier systems of which Declarant was aware.

In paragraph 8, Declarant discusses the commercial release of the device which was described in paragraphs 4-7.

In paragraph 9, Declarant discusses the pricing of the system and the volume sales thereof and gross income therefrom, from the commercial release to the present, and opines that “successful sales of this handpiece is directly attributable to the claimed design parameters.”

While the Declaration is noted, Declarant’s opinions regarding the non-obviousness of the commercial device developed by Cutera, Inc. is not convincing. Firstly, it is noted that Declarant is an employee of assignee, this reduces the weight accorded determinations of non-

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obviousness made thereby. Further, this proper criteria for obviousness under 35 U.S.C. 103(a) is the knowledge of one of ordinary skill in the art, including all publications in the field of the invention, not merely devices commercially available. Lastly, while Declarant's opinion regarding the reason for the sales figures discussed are noted, there is insufficient information in the Declaration to firmly establish a nexus between the commercial success of the device and the claimed attributes thereof, both because there is no information on competing products, relative pricing, advertising budgets, etc to name only a few variables affecting commercial success, but also because the claimed invention is related to a method, not to a device as discussed in the Declaration.

Claims 15-17, 22, 33, 42, and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,120,497 to Anderson et al in combination with U.S. Patent Application Publication US 200410093042 to Altshuler et al. ('3042) and U.S. Patent Application Publication US 200210173780 to Altshuler et al. ('3780). Anderson et al. teach a method for treating wrinkles with radiation at depths from 100 microns to 1.2 millimeters (overlaps claim depth) using laser or incoherent radiation and specifically discloses the known property of collagen to shrink at temperatures from 60°C to 70°C (see column 5, lines 19-41), as well as the desirability of using wavelengths in the range of 1.3 to 1.8 microns, e.g. a band principally between 1,300 nm and 1,800 nm (see column 3, lines 28-37), and provides for cooling before and during the application of radiation to control the depth and temperature of treatment (see column 5, line 66 to column 6, line 14). Altshuler et al. '3042 teach a method and apparatus for treating tissue with light above 1050 nm which can be generated by an incandescent source (non-invasive wrinkle removal) in a region at depth by applying optical

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radiation thereto of a wavelength able to reach the depth of the region and of a selected relatively low power for a duration sufficient for the radiation to effect the desired treatment while concurrently cooling tissue above the selected region to protect such tissue (abstract). The irradiation source (Fig. 1, # 1) may be a radiant lamp, a halogen lamp, an incandescent lamp, an arc lamp, a fluorescent lamp, a light emitting diode, a laser (including diode and fiber lasers), the sun or other suitable optical energy source (paragraph 0044). Cooling is provided by a contact plate (Fig. 1, # 8) and may be made out of a suitable heat transfer material, and also, where the plate contacts tissue, of a material having a good optical match with the tissue. Sapphire is disclosed as an example of a suitable material for the plate. In some embodiments, the contact plate may have a high degree of thermal conductivity, for example, to allow cooling of the surface of the tissue by cooling mechanism (paragraph 0050). The irradiation time may vary from approximately 2 seconds to approximately 2 hours (paragraph 0012). The treatment times overlap those claimed and one skilled in the art would use a time appropriate to achieve the desired temperature based on the operating parameters of the radiation source. Cooling may be applied concurrently with the irradiation or prior to irradiation (paragraph 0011). The cooling of the epidermal layer in conjunction with irradiation inherently yields an inverted temperature gradient. Sensors or other monitoring devices may also be embedded in cooling mechanism, for example, to monitor the temperature, or determine the degree of cooling required by tissue, and be manually or electronically controlled (paragraph 0051). A skilled artisan knows that such control may be via a simple timer or feedback mechanism such as a temperature sensor and typically provides for a means of notification that the process has ended. Indicator lights and audible tones are known and obvious. Altshuler et al. '3042 further teach an irradiation

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wavelength of from 1050 to 1250 nanometers (paragraph 0010), which is well known to penetrate tissue from about 2-5 millimeters. A filter (Fig. 1, # 3) is included for wavelength selection. Altshuler et al. '3042 do not disclose cooling after termination of the treatment radiation. Altshuler et al. '3780 teach an apparatus and method for irradiating tissue with a cooled waveguide for cooling the tissue before, during and after irradiation. This clearly teaches a predetermined time after irradiation termination or the cooling would continue indefinitely. Neither Altshuler et al. '3042 nor Altshuler et al. '3780 disclose the specific temperature at which collagen shrinks. It would have been obvious to the artisan of ordinary skill to one skilled in the art to continue cooling the tissue following radiation as taught by Altshuler et al. '3780 while heating collagen in the method taught by Anderson et al., since importance of cooling to avoid damage to peripheral area and it is considered obvious to one of skill in the art, and such person would continue cooling to limit such damage, and to employ the incandescent source and filters of Altshuler et al. '3042 since Anderson recognizes that absorption occurs over a range of wavelengths. Thus, the combination of the known methodologies would clearly yield a predictable result. Both Altshuler et al. references provide a handpiece. To provide switches and indicators necessary for operation on the handpiece is well known and obvious, thus producing a method such as claimed.

Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al in combination with Altshuler et al. ('3042) and Altshuler et al. ('3780). as applied to claim 15 above and further in view of U.S. Patent 5,885,274 to Fullmer et al. The Altshuler et al. and Anderson et al. teachings are discussed above, but do not teach the importance of the temperature of the filament. Fullmer et al. disclose a filament lamp for use in dermatological

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treatments including the use of a simmer voltage to maintain the temperature of the filament to allow faster rise time of the light pulses and to enhance the short pulses by the filament being in a warm condition (Col. 7, lines 42-45). It would have been obvious to one skilled in the art to use the simmer pulse (long pulse) as taught by Fullmer et al. in the method of Altshuler et al. '3042 in view of Altshuler et al. '3780 in Anderson et al. to improve the efficiency of the light source pulse integrity as suggested by Fullmer et al., thus producing a method such as claimed.

Claim 41 is rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al in combination with Altshuler et al. ('3042) and Altshuler et al. ('3780). as applied to claim 15 above and further in view of U.S. Patent Application Publication US 200510107850 to Vaynberg et al. The Altshuler et al. teachings are discussed above, but do not teach control of the light source using detected light from the source. Vaynberg et al. disclose a method and system for skin rejuvenation by heating collagen (paragraph 0037) using light from a non-coherent source. The light source is controlled using a light sensor (Fig. 1, # 135) that provides feedback to a controller (Fig. 1, # 130) to alter the pulse parameters (Paragraph 00 18). It would have been obvious to one skilled in the art to use the optical feedback as taught by Vaynberg et al. in the method of Altshuler et al. '3042 in view of Altshuler et al. '3780 in view of Anderson et al. to provide positive control of the treatment parameters, thus producing a method such as claimed.

Applicant's arguments with respect to claims 15-17, 22, 33, and 40-43 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to david shay whose telephone number is (571) 272-4773. The examiner can normally be reached on Monday through Thursday from 6:30 a.m. to 5:00 p.m.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson, can be reached on Monday through Friday from 7:00 a.m. to 3:30 p.m. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/david shay/

Primary Examiner, Art Unit 3769